

PATENT

Docket No. 2026-4237US2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Smyth-Templeton, N. et al. Group Art Unit: TBA
Con. of
Serial No. : 09/242,190 Examiner: TBA
Filed : November 20, 2001
For : NOVEL LIPOSOME COMPLEXES FOR INCREASED
SYSTEMATIC DELIVERY

PRELIMINARY AMENDMENT

Commissioner for Patents
2900 Crystal Dr.
Arlington, VA 22202-3513

Dear Sir:

Prior to examination and calculation of the filing fee, please amend the application as follows.

IN THE CLAIMS

Please amend the following claims:

9. (amended) The liposome of claim 15, wherein the biologically active agent is DNA, thereby forming a DNA sandwich composite liposome.

10. (amended) The liposome according to claim 9 further comprising a targeting ligand to the exterior surface of said DNA-sandwich composite liposome.

Please add the following new claims:

15. (new) An invaginated vase-like liposome produced by the steps comprising:

- i) heating 1,2-bis(oleoyloxy)-3-(trimethylammonio)-propane and at least one cholesterol or cholesterol derivative forming heated lipid components;
- ii) hydrating said heated lipid components forming hydrated lipid components;
- iii) sonicating said [heated] hydrated lipid components forming sonicated lipid components;
- iv) extruding said sonicated lipid components sequentially through filters of decreasing pore size; and
- v) adding a biologically active agent to said extruded lipid components forming invaginated vase-like liposomes.

16. (new) A composite liposome comprising a first lipid bilayer liposome having an outer surface; a biologically active agent surrounding the outer surface of said first lipid bilayer liposome; and a second lipid bilayer encapsulating the biologically active agent, wherein said composite liposome forms an invaginated vase-like structure.

17. (new) The composite liposome of claim 16, wherein the biologically active agent is DNA.

REMARKS

Applicants respectfully request favorable reconsideration in view of the herewith presented amendments and remarks. The amended claims do not introduce new subject matter, nor do the amendments raise new issues of

patentability. Entry of this amendment is respectfully requested. It is believed that entry of the amendment places the instant claims in condition for allowance. If the Examiner decides to maintain the rejection of this application, entry of the amendment will reduce the number of issues remaining for appeal.

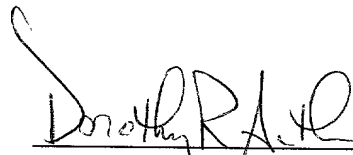
Applicants respectfully request favorable consideration of the present application and claims. Early and favorable action by the Examiner is earnestly solicited.

No additional fee is believed to be necessary.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Date: November 20, 2001

By:


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VERSION WITH MARKINGS SHOWING CHANGES

As required by 37 C.F.R. §1.121, a “marked up” version of the replacement claim is provided herewith, where additions are indicated by underlining and deletions by brackets.

9. (amended) The liposome of claim [8] 15, wherein the biologically active agent is DNA, thereby forming a DNA sandwich composite liposome.

10. (amended) The liposome according to claim 9 further comprising[, adding] a targeting ligand [thereby decorating] to the exterior surface of said DNA-sandwich composite liposome [with the ligand].

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17. (new) The composite liposome of claim 16, wherein the biologically active agent is DNA.

REMARKS

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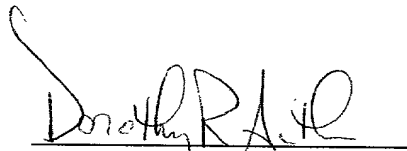
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